

WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Agriculture TITLE-SERIES: 61-40

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: WV Exempted Dairy Farms and Milk and Milk

Products Processing Rule

CITE STATUTORY AUTHORITY: §19-11E-8

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 09/20/2020 12:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Amie Minor

ADDRESS: WV Dept of Agriculture/READ

1900 Kanawha Boulevard, East Charleston, WV 25305

EMAIL: aminor@wvda.us

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: Yes

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:
Establishes operating rules and procedures for WV dairy farms producing pasteurized milk
SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:
Establishing labeling requirements
SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE: A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:
n/a
B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS: n/a
C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year				
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)		
1. Estimated Total Cost	0	0	0		
Personal Services	0	0	0		
Current Expenses	0	0	0		
Repairs and Alterations	0	O	О		
Assets	0	0	0		
Other	0	0	0		
2. Estimated Total Revenues	О	О	0		

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	EXPLANATION	~ ~ ~ ~ ~ <i>~</i> ~ <i>/</i>	***********	/18:A:::::::::::::::::::::::::::::::::::	~ * ! ~ ~ ~ * * ! ~ ~ ~	
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n/a

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Norman Bailey -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

61CSR40

TITLE 61 LEGISLATIVE RULE DEPARTMENT OF AGRICULTURE

SERIES 40 WV EXEMPTED DAIRY FARMS and MILK AND MILK PRODUCTS PROCESSING RULES

§61-40-1. General.

- 1.1. Scope. This legislative rule establishes operating rules and procedures for West Virginia dairy farms producing pasteurized milk that do not meet the Grade A PMO or the Manufacture Grade Milk in the state, and from which all milk and dairy products are to be sold only in the state of West Virginia.
 - 1.2. Authority. W. Va. Code §19-11E-8.
 - 1.3. Filing Date. April 30, 2020.
 - 1.4. Effective Date. April 30, 2020.
- 1.5. Sunset Date. This rule shall expire and have no further force and effect five years from its effective date.

§61-40-2. Definitions.

- 2.1. "Commissioner" means the Commissioner of Agriculture of the State of West Virginia or his or her duly authorized agent or designee.
- 2.2. "Acceptable milk" means milk, or cream from the milk, which meets the requirements as to sight and odor, sediments, bacterial content, inhibitory substances, and which has been produced in compliance with the provisions set forth in this Rule.
- 2.3. "Barnyard" means an enclosed or unenclosed area adjacent to the milking barn which may include housing areas and feedlots in which the animals may congregate.
- 2.4. "Dairy farm" or "farm" means a place or premises where one or more milking animals are kept, a part or all of the milk produced on the farm being used in the production of milk or dairy products by the incorporation of approved methods.
- 2.5. "Inspection" means the inspection of the dairy farm premises, buildings, animals, equipment, utensils, water supply, and facilities and procedures used in the production of milk and/or dairy products solely in the state of West Virginia.
- 2.6. "Inspector" means a qualified, trained person employed by the West Virginia Department of Agriculture or any person designated by the Commissioner to inspect dairy farms and processing facilities.
- 2.7. "Inhibitory substances" means antibiotics and pesticides not registered for use on lactating dairy animals, and other substances as determined by the Commissioner.

- 2.8. "Milk" means the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy hooved lactating mammals. Hooved mammals' milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals for the purpose of this rule, include, but are not limited to, the members of the Order Cetartiodactyla such as Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.). Milk shall be produced according to the sanitary standards of this rule.
- 2.9. "Milkhouse" or "milkroom" means a room at the facility for handling and cooling milk and for washing and storing milking equipment and utensils.
- 2.10. "Person" means any individual, firm, co-partnership, corporation, cooperative association, cooperative corporation or unincorporated association.
- 2.11. "Producer" means the person or persons who exercise control over the production of milk on a West Virginia dairy farm, where the milk or the cream from the milk is used to manufacture fluid milk or dairy products.
- 2.12. "Sanitize" or "sanitization" means the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such method or substance shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Commissioner.
- 2.13. "Milk Products" means all milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk, cottage cheese and dry curd cottage cheese, whey and whey products, modified versions of all the preceding products, modified versions of milk products packaged in combination with food(s) not yet included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols", and all other products deemed a dairy product by the commissioner. For the purpose of this rule, Cheese and Related Cheese Products shall be included as a milk product.
- 2.14. "Cheeses and Related Cheese Products" means those items set forth in Title 21 Food and Drugs Chapter 1 Food and Drug Administration Department of Health and Human Services Subchapter B Food for Human Consumption Part 133 Cheeses and Related Cheese Products Subpart A- General Provisions and Subpart B- Requirements for Specific Standardized Cheese and Related Products.
- 2.15. "Pasteurization", "pasteurized", or similar terms means the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) of the temperatures given in this rule.
- 2.16. "Milk and milk products processing facility" means any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution in West Virginia.

§61-40-3. Minimum quality standards.

- 3.1. Acceptable milk for the manufacture of milk and/or dairy products shall meet the following standards:
- 3.1.1. Sight and odor: The milk shall be free from visible foreign matter. It shall not be curdled, ropy, bloody, or mastitic as indicated by sight or odor. It shall be free from feed odors or other objectionable odors;
- 3.1.2. Temperature: Milk shall be cooled to 45 degrees Fahrenheit or lower within two hours after milking and shall be maintained at 45 degrees Fahrenheit or lower until shipped or used to manufacture milk products;
- 3.1.3. Bacterial limits: Milk from an individual producer shall not exceed 1,000,000 bacterial count per milliliter as determined by standard plate count;
 - 3.1.4. Inhibitory substances: No inhibitory substances are permitted in milk; and
- 3.1.5. Sediment: Milk should not have more than 1.5 mg of sediment as determined by the Standard Methods for the Examination of Dairy Products.

§61-40-4. Minimum testing requirements.

- 4.1. At least once each month at irregular intervals the producer shall take samples of the milk. The samples shall be tested for compliance with the standards set forth in this rule and are subject to the abnormal milk provisions of this rule. Additional samples may also be collected by an inspector.
- 4.2. Samples shall be analyzed at an approved official or officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with rules set forth by the Commissioner.
- 4.3. The Commissioner should arrange to visit each producer who continually does not meet the requirements for acceptable milk, for the purpose of inspecting equipment, utensils, and facilities at the farm and to offer constructive assistance for improvement in the quality of the milk.
- 4.4. Concurrent with all test results made to a producer regarding bacteria counts, sediment, or inhibited substances, the laboratory shall send a copy of the results to the Commissioner.

§61-40-5. Inhibitory substances.

5.1. If the milk from a dairy farm contains an inhibitory substance, the producer shall not use any more milk produced by such farm for at least two days following the test to ship or manufacture milk products. The producer shall not use any more milk until the production from the farm has been found to be free of inhibitory substances. The two-day exclusionary provisions cited shall be increased to three days for a repeat violation within six months and shall be increased to four days for subsequent violations within that period.

§61-40-6. Abnormal milk.

- 6.1. A producer shall not use for manufacturing milk which is found to be abnormal by sight or odor, which is from animals that show evidence of the secretion of abnormal milk in one or more quarters, or which is from animals that have consumed chemical, medicinal, or radioactive agents that may be secreted in the milk.
- 6.2. Equipment, containers, and utensils used to handle abnormal milk shall be cleaned and sanitized by the producer before they are used for milk for manufacturing purposes. The equipment shall meet the construction requirements set forth in this Rule.
- 6.3. Milk from animals treated with or exposed to pesticides not approved for use on dairy animals by the U. S. Environmental Protection Agency shall not be used for manufacturing purposes until the milk has been tested and found acceptable by the Commissioner.
- 6.4. When a confirmatory test on a routine sample indicates a somatic cell count above 1,000,000 cells per milliliter, the Commissioner shall send written notification of the unsatisfactory cell count to the producer.
- 6.5. When two out of the last four routine samples have a somatic cell count above 1,000,000 cells per milliliter, the Commissioner shall send a written notice of the counts to the producer and a representative of the Commissioner shall contact the producer to endeavor to determine and eliminate the source of the violative cell count.

§61-40-7. Adulteration.

- 7.1. Milk is considered to be adulterated if it contains any poisonous or deleterious substances, does not meet the quality standards set forth in this rule, has been produced, processed, or held under unsanitary conditions, contains added water, or contains bacteria in excess of those standards set forth in this rule.
 - 7.2. The producer shall not use milk if it is adulterated.

§61-40-8. Milking bar or parlor construction and maintenance.

- 8.1. Each farm shall have a milking barn or milking parlor of adequate size and arrangement to permit normal sanitary milking operations. Such milking barn or parlor shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material. The milking barn or parlor construction must be approved by the commissioner before milking can begin.
- 8.2. The milking barn or parlor shall be kept clean, with the manure removed daily and stored to prevent access of animals to the accumulation of the manure. No swine, fowl or other domestic or wild animals shall be permitted in any part of the milking area.
- 8.3. If milk is exposed during straining or transferring in the milking areas it shall be protected from falling particles from areas above the milking facility.

§61-40-9. Milking barn or parlor cleanliness.

- 9.1. The interior of the milking barn or parlor shall meet the following standards of cleanliness:
 - 9.1.1. The interior of the facilities shall be kept clean;
- 9.1.2. The bedding material, if used, shall not contain more manure than that which has accumulated since the previous milking;
 - 9.1.3. The gutter shall be kept reasonably clean, with manure removed daily; and
 - 9.1.4. All pens and stalls, if not separated from the milking barn or parlor shall be kept clean.

§61-40-10. Barnyard.

- 10.1. A barnyard shall meet the following requirements:
- 10.1.1. The barnyard shall be graded and drained. Depressions and soggy areas shall be filled and lanes shall be reasonably dry.
- 10.1.2. Approaches to the barn door and the surroundings of stock watering and feeding stations shall be solid to the footing of the animals.
- 10.1.3. Wastes from the barn or milkhouse shall not be allowed to pool in the barnyard. Barnyards which are muddy due to recent rains do not violate this section.
- 10.1.4. Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in the barnyard in such a manner as to permit the soiling of udders and flanks. Housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) are considered a part of the barnyard. Manure packs shall be solid to the footing of the animal.
- 10.1.5. Barnyards shall be kept reasonably free of droppings. Droppings shall not be allowed to accumulate in piles that are accessible to the animals.
 - 10.1.6. The yard or loafing area shall be of ample size to prevent overcrowding.

§61-40-11. Milkhouse construction and facilities.

- 11.1. The producer may provide a milkhouse conveniently located and properly constructed, lighted, and ventilated for handling and cooling milk and for washing, handling, and storing the equipment and utensils. Other products which would be likely to contaminate milk, or otherwise create a public health hazard, shall not be handled in the milkhouse.
 - 11.2. If the farm has a milkhouse, it shall meet the following construction requirements:
 - 11.2.1. The milkhouse shall be equipped with wash and rinse vats and a utensil rack and have an

adequate supply of hot and cold water available for cleaning milking equipment. If the milkhouse is part of the barn or other building, it shall be partitioned, screened, and sealed to prevent the entrance of dust, flies, or other contamination. A milking parlor used strictly as a milking facility in combination with a milkhouse, when properly equipped, arranged and maintained, need not be partitioned.

- 11.2.2. Concentrates and feed, if stored in the building, shall be kept in a tightly covered box or bin.
- 11.2.3. The floor of the building may be of concrete or other impervious material. The floor slopes shall drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.
- 11.2.4. The liquid wastes shall be disposed of in a sanitary manner. All floor drains shall be accessible and shall be trapped if connected to a sanitary sewer.
- 11.2.5. Walls and ceilings shall be constructed of smooth dressed lumber or similar material, be well painted with a light-colored washable paint, and be in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tiles, cement block, brick, concrete, cement plaster, or similar materials of light color may be used as long as the surfaces and joints are smooth and easily cleaned.
- 11.2.6. Windows and solid doors shall be closed during dusty weather. Windows and doors shall be properly screened. All outside doors shall open outward and have effective means to prevent the entrance of flies.
- 11.2.7. The milkhouse shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.
- 11.2.8. Vents and light fixtures shall be installed in a manner to prevent the contamination of milk and clean utensils.
- 11.2.9. There shall be no direct opening into any barn, stable, or room used for domestic purposes, except that an opening between the milkhouse and milking parlor is permitted when a tight fitting, self-closing, solid door, hinged to be single or double acting, is present.

§61-40-12. Milkhouse cleanliness.

- 12.1. If the farm has a milkhouse, the producer shall meet the following requirements:
- 12.1.1. The milkhouse structure, equipment, and other milkhouse facilities shall be kept clean at all times.
 - 12.1.2. The milkhouse and its appurtenances shall be free of trash, animals, and fowl.
- 12.1.3. Pesticides or unapproved antibiotics shall not be stored in the milkhouse. When pesticides or antibiotics are used, they shall be used in accordance with label instructions so as to prevent contamination of the milk.

§61-40-13. Milking utensils and equipment - construction, cleaning, storage, and handling.

- 13.1. Construction of utensils and equipment shall meet the following requirements:
- 13.1.1. All multiuse utensils, equipment, and containers which are exposed to milk or milk products shall be made of smooth, impervious, nonabsorbent, safe materials of the following types:
 - 13.1.1.a. Stainless steel of the AISI (American Iron and Steel Institute) 300 series;
 - 13.1.1.b. Equally corrosion resistant nontoxic metal;
 - 13.1.1.c. Heat resistant glass; or
- 13.1.1.d. Plastic or rubber and rubber like materials which are relatively inert, resistant to scratching, scoring, decomposition crazing, chipping, and distortion under normal use conditions. The materials shall be nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, and may not release component chemicals or impart flavor or odor to the product. The materials shall maintain their original properties under repeated use conditions.
- 13.1.2. Single-service articles shall be manufactured, packaged, transported, and handled in a sanitary manner.
 - 13.1.3. Articles intended for single-service use shall not be reused.
 - 13.1.4. All containers, equipment, and utensils shall be free of breaks and corrosion.
- 13.1.5. All joints in the containers, equipment, and utensils shall be smooth and free from pits, cracks, and inclusions.
- 13.1.6. Strainers shall be of perforated metal design or constructed to utilize single-service strainer media.
- 13.1.7. All milking machines, including heads, milk claws, milk tubing, and other milk contact surfaces, shall be easily cleaned and inspected.
 - 13.2. Utensils and equipment shall meet the following cleanliness requirements:
- 13.2.1. The contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk or milk products shall be cleaned after each use.
- 13.2.2. The contact surfaces of all multiuse containers, equipment, and utensils shall be sanitized immediately prior to use for the handling, storage, or transportation of milk or milk products.
 - 13.3. Utensils and equipment shall be stored in the following manner:
 - 13.3.1. All milk containers, utensils, and equipment, including milking machine vacuum hoses, shall be stored in a sanitizing solution or on racks until used.

- 13.3.2. All milk containers, utensils and equipment shall be stored in a clean and properly ventilated area.
 - 13.3.3. Equipment shall be stored to drain completely.
- 13.3.4. Strainer pads, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.
- 13.4. Utensils and equipment handling shall meet the following requirements:
- 13.4.1. After sanitation, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product contact surface.
- 13.4.2. Sanitized product contact surfaces shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.
- 13.4.3. Any sanitized product contact surface which has been exposed to contamination shall be cleaned and sanitized again prior to being used.

§61-40-14. Milking - flanks, udders, and teats.

- 14.1. Milking practices shall meet the following requirements:
 - 14.1.1. Milking shall be done in an approved milking barn or parlor.
- 14.1.2. The animals' hair on flanks, bellies, tails, and udders shall be shortened as often as necessary to facilitate cleaning of those areas and shall be free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking, or as to adulterate the milk in any manner.
- 14.1.3. Udders and teats of all milking animals shall be cleaned and treated with a sanitizing solution and shall be relatively dry just prior to milking.
 - 14.1.4. Wet hand milking will be allowed when approved by the Commissioner.

§61-40-15. Milking - surcingles, milk stools, and anti-kickers.

15.1. Surcingles, milk stools, and anti-kickers shall be kept clean and shall be stored above the floor in a clean place in the milking barn, stable, parlor, or milkhouse when not in use.

§61-40-16. Protection from contamination.

- 16.1. Protection from contamination requires compliance with the following:
- 16.1.1. Equipment and operations shall be located within the milking barn and milkhouse to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and

utensils by splash, condensation, or manual contact.

- 16.1.2. All milk which has overflowed, leaked, spilled, or been improperly handled shall be discarded.
- 16.1.3. All product contact surfaces of containers, equipment, and utensils shall be covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination.
- 16.1.4. When milk is poured or strained in the milking barn, the receiving receptacle shall be raised above the floor (as on a dolly or cart) or placed at a distance from the animals to protect it from manure or splash. The receptacle shall have a tight-fitting cover which shall be closed except when milk is being poured.
- 16.1.5. Each pail or container of milk shall be transferred immediately from the milking barn to the refrigerated storage facility.
- 16.1.6. Pails, cans, and other equipment containing milk shall be properly covered during transfer and storage.
- 16.1.7. Antibiotics and medicines shall be stored in such a manner that they cannot contaminate the milk or milk product contact surfaces of the equipment, containers, or utensils.

§61-40-17. Personnel - hand washing facilities.

- 17.1. The following hand washing facilities for personnel are required:
- 17.1.1. Hand washing facilities shall be located convenient to the milking barn, parlor, or flush toilet.
 - 17.1.2. Hand washing facilities shall include soap or detergent, water, and single use towels.
- 17.1.3. Hand washing facilities shall be kept in good repair, clean, and shall not be used for storage.

§61-40-18. Personnel - cleanliness and health.

- 18.1. All persons shall comply with the following:
- 18.1.1. Hands shall be washed clean and dried with a sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities.
- 18.1.2. Any person milking an animal shall wear clean outer garments while milking or handling milk, milk products, milk containers, equipment or utensils;
- 18.1.3. No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm or milk products facility in any capacity which brings him or

her into contact with the production, handling, storage, or transportation of milk or milk products, containers, equipment, or utensils. No dairy farm operator or milk products producer shall employ in any capacity any person having or suspected of having a disease in a communicable form, or being a carrier of such disease. Any producer who suspects that any employee or family member has contracted any disease in a communicable form, or has become a carrier of the disease, shall notify the Commissioner immediately.

- 18.1.4. When reasonable cause exists to suspect the possibility of transmission of infection from any person handling milk or milk products, the Commissioner may require any or all of the following measures:
 - 18.1.4.a. The immediate exclusion of the affected person from milk or milk products handling;
 - 18.1.4.b. The immediate exclusion of the milk or cheese supply concerned from distribution and use; and
 - 18.1.4.c. Adequate medical and bacteriological examination of the person, and of his or her associates.

§61-40-19. Insect and rodent control.

- 19.1. Effective measures shall be taken to prevent the contamination of milk and milk products, containers, equipment, and utensils by insects or rodents, and by chemicals used to control the vermin.
- 19.2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds and free stall housing shall be properly bedded and managed to prevent fly breeding.
 - 19.3. Milkhouses and all buildings shall be kept free of insects and rodents.
 - 19.4. Milkhouses and all buildings shall be effectively protected against the entrance of vermin.
- 19.5. Insecticides not approved for use in a milkhouse or dairy facility shall not be stored in such facilities.
- 19.6. Only insecticides and rodenticides approved for use by the Commissioner and registered with the United States Environmental Protection Agency shall be used for insect and rodent control.
- 19.7. Insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions so as to prevent the contamination of milk and milk products, containers, equipment, utensils, feed and water.

§61-40-20. Farm inspection.

20.1. Each farm shall be inspected for compliance with this rule at least once a year. Inspections may be conducted more frequently if necessary, to achieve compliance with the provisions of this Rule, or as deemed necessary by the commissioner.

§61-40-21. Animal health.

- 21.1. All animals' milk for processing milk or milk products shall be from herds under a brucellosis eradication program which meets one of the following conditions, or eradication program for animal health:
 - 21.1.1. The herd is located in a Certified Brucellosis-Free Area as defined by the United States Department of Agriculture and enrolled in the testing program for the areas;
 - 21.1.2. The herd is located in a Modified Certified Brucellosis Area as defined by the United States Department of Agriculture and enrolled in the testing program for the areas;
 - 21.1.3. The herd meets United States Department of Agriculture requirements for an individually certified herd;
 - 21.1.4. The herd is participating in a milk ring testing program which is conducted on a continuing basis at intervals of not less than every three (3) months or more than every six (6) months with individual blood tests on all animals in herds showing suspicious reactions to the milk ring test; or
 - 21.1.5. The herd has an individual blood agglutination test annually with an allowable maximum grace period not exceeding two (2) months.
- 21.2. All animals' milk for manufacturing milk products shall be from herds which are located in a Modified Accredited Tuberculosis Area as determined by the United States Department of Agriculture. A Modified Accredited Tuberculosis Area requires all dairy herds to be tested every six (6) years with an allowable maximum grace period of two (2) months. Herds located in an area that fails to maintain accredited status shall be accredited by the United State Department of Agriculture as tuberculosis free, or shall pass an annual tuberculosis test.
- 21.3. For diseases other than brucellosis and tuberculosis the Commissioner may require any physical, bacteriological, or chemical tests he or she determines necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of the Commissioner. Any producer owning a diseased animal disclosed by the test shall dispose of the animal as the Commissioner directs.

§61-40-22. Farm exclusion.

- 22.1. No farm shall process milk or milk products using raw milk from a dairy farm that is not in compliance with the provisions of this Rule.
- 22.2. In the event of noncompliance with this Rule or in the event of a refusal by a producer to allow an inspection of the dairy farm by an inspector of the West Virginia Department of Agriculture or designee, the milk from the dairy farm shall not be used to process milk or milk products until such time as the farm is found to be in compliance and/or access to inspect the dairy farm is permitted.

§61-40-23. Milk and milk products processing facility.

- 23.1. The milk and milk products processing facility shall meet the following construction and facility requirements:
- 23.1.1. A milk and milk products facility shall be conveniently located and properly constructed, lighted, and ventilated to prevent any contamination of milk or milk products, ingredients, containers, utensils, and equipment. Walls and ceilings shall be finished with smooth, washable, impervious materials, and shall be kept in good repair.
- 23.1.2. Products which would be likely to contaminate milk or milk products or otherwise create a health hazard shall not be handled in the milk products facility.
- 23.1.3. The milk and milk products facility shall be equipped to provide for the washing and sanitizing of equipment and utensils with an adequate supply of hot and cold water; All sanitary piping, fittings and connections which are exposed to milk and milk products or from which liquids may drip, drain or be drawn into milk and milk products shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material, which is approved for milk product-contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.
- 23.1.4. The liquid wastes shall be disposed of in a sanitary manner. All drains shall be trapped if connected to a sanitary sewer.
- 23.1.5. The milk products facility shall be constructed in a manner which will provide for adequate cleaning of ceilings, walls, and floors; all doors and windows shall be provided to prevent the access of insects and rodents. All openings shall have solid doors and adequate windows.
- 23.1.6 All rooms for processing milk and milk products shall be separate, and not direct entry into a stable, holding area, or other room used for domestic purposes.
- 23.1.7. Only equipment directly related to processing operations or the handling of containers, utensils and equipment is permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.
- 23.1.8. All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment shall be clean.
- 23.1.9. No trash, solid waste or waste dry product shall be stored within the milk plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.
- 23.1.10. The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use.
- 23.1.11. After cleaning, all multi-use milk or milk product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

- 23.1.12. Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.
- 23.1.13. All milk or milk products or ingredients that have been spilled, overflowed, mishandled or leaked shall be discarded, including all products drained from processing equipment and the end of a run, or otherwise not used in the original processing of milk or milk products.

§61-40-24. Water supply.

- 24.1. Any dairy farm or milk and milk products processing facility's water supply shall be properly located, protected, and operated. It shall be easily accessible, ample, and of safe sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from an approved public source or from a spring, dug well, driven well, bored well, or drilled well, that complies with the standards of the West Virginia Department of Health and Human Resources.
 - 24.2. Water samples will be taken and tested to meet standards set by the Commissioner.

§61-40-25. Pasteurization of milk and milk products.

25.1. All milk and milk products, except eggnog, shall be pasteurized to one (1) of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Batch (Vat) Pasteurization			
Temperature	Time		
63°C (145°F)*	30 minutes		
Continuous Flow (HTST and HHST)			
Pasteurization			
Temperature	Time		
72°C (161°F)*	15 seconds		
89°C (191°F)	1.0 second		
90°C (194°F)	0.5 seconds		
94°C (201°F)	0.1 seconds		
96°C (204°F)	0.05 seconds		
100°C (212°F)	0.01 seconds		

^{*}If the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).

25.2. Eggnog shall be heated to at least the following temperature and time specifications:

Table 3. Pasteurizatio	on Temperature vs. Time			
Batch (Vat) Pasteurization				
Temperature	Time			
69°C (155°F)	30 minutes			
Continuous Flow (HTST) Pasteurization				
Temperature	Time			
80°C (175°F)	25 seconds			
83°C (180°F)	15 seconds			

- 25.3. There shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products not completely separated from pasteurized milk and milk products shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of Pasteurization.
 - 25.4. Water that comes in contact with pasteurized milk and/or milk products shall:
 - 25.4.1. Meet at least the minimum times and temperatures provided for in the definition of Pasteurization in equipment, or
 - 25.4.2. Have undergone an equivalent process found acceptable by the WVDA
- 25.5. A producer must provide means to prevent contamination of milk and/or milk products, containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.
- 25.6. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.
- 25.7. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

§61-40-26. Food allergens.

- 26.1. A milk or milk product processing facility shall:
- 26.1.1. Ensure the protection of milk and/or milk products from allergen cross-contact, including during storage, handling and use.
- 26.1.2. Label the finished milk and/or milk products, ensuring that the finished milk and/or milk products is not misbranded under Section 403(w) of the Federal Food, Drug and Cosmetic Act with an undeclared food allergen.

- 26.1.3. Prevent food allergen cross-contact between insanitary objects, personnel, and non-milk allergen-containing foods and milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces.
- 26.2. Raw materials and ingredients that are food allergens, and rework that contains food allergens, shall be identified and held in a manner that prevents food allergen cross-contact.

§61-40-27. Holding and distribution of human food by-product for use as animal food.

- 27.1. Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be held under conditions that will protect against contamination as appropriate for their final use in animal food.
- 27.2. Labeling that identifies the by-product shall be affixed to or accompany human food by-products for use as animal food when distributed.
- 27.3. Shipping containers (e.g., totes, drums, tubs, etc.) and bulk vehicles used to distribute human food by-products for use as animal food shall be appropriate for transporting human food by-products for use as animal food and protecting against contamination during transport.

§61-40-28. Permit to operate.

- 28.1. It is unlawful for any person who does not possess a permit from the Department of Agriculture to operate a dairy farm or a milk and milk products processing facility which produces and offers for sale milk or milk products as covered under the provisions of this Rule.
- 28.2. The producer and the milk or milk products processing facility shall apply for a permit on forms prescribed and furnished by the Commissioner. All permits expire December 31 of each year.

§61-40-29. Labeling of Milk and Milk Products.

- 29.1. Milk or milk products offered for sale shall have the following information on the label:
- 29.1.1. Product Identity. Product identity shall include the common or usual name of the product, the name established for that product by law or regulation, or a descriptive name of the product when the nature of the food is obvious.
 - 29.1.2. Net Quantity. Net quantity must be included on each container or package.
 - 29.1.2.1. For all milk products other than fluid milk products and ice cream, the net quantity must be listed in ounces and be preceded by the phrase "Net Weight".
 - <u>29.1.2.2.</u> Labels for fluid milk products and ice cream do not need to include the wording "net weight" and may list net quantity in terms of pints, quarts, or gallons, as appropriate.
- 29.1.3. Name and Address of the Manufacturer. The address listed should be the address where the milk or milk product is pasteurized, ultra-pasteurized, aseptically processed or packaged, retorted

- after packaging, or condensed and/or dried.
- 29.1.4. Identifying Numbers. Each container or package shall have a code number, lot number, or other mark identifying the contents of the package with a specific date, run, or batch of the product.
 - 29.1.5. Dates. Each container or package shall have a "packaged on" or expiration date.
- 29.1.6. Refrigeration Information. The words "Keep Refrigerated", or "Keep Refrigerated After Opening" in the case of aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products, must be included on each product.
- 29.1.7. Animal Source. The common name of the hooved mammal producing the milk shall precede the name of the milk or milk product when the product is, or is produced with, the milk of any animal other than cattle. For example, "Goat Milk", "Sheep Milk", "Water Buffalo Milk", or "Camel Milk", or "Goat Ice Cream", "Sheep Butter", "Camel Cream", etc. would be appropriate labels.
- 29.1.8. West Virginia Exempt Dairy Product Status. The words "A WV Exempt Dairy Product", a "West Virginia Exempt Dairy Product," or some other approved language indicating that the milk or milk product was produced under the authority granted by this rule must be on the label in a font and size consistent with, or larger than, the fonts used elsewhere on the label of the container or package.
- 29.1.9. Ingredients List (for products containing more than one ingredient). All ingredients shall be listed in descending order by predominance of weight. Multi-component ingredients may be listed parenthetically unless the weight is known on each sub ingredient.
- 29.1.10. Allergens. Allergen labeling is required if one of the major allergens, as identified by the FDA, is not listed by its common or usual name in the ingredient list. All allergens can be listed after the ingredient list by placing the words "Contains:" followed by the common name of the food allergen.
 - 29.1.11. Any additional information required by the commissioner.